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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,454	09/17/2003	Mark L. Jenson	760-68	4333

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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,454	JENSON, MARK L.	
	Examiner	Art Unit	
	Ann Schillinger	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-22 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sogard et al. (U.S. Patent No. 6,139,573). Sogard et al. discloses all of the following regarding claim 1: a composite device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising: a first polymeric liner (14; col. 9, lines 59-63); a second polymeric liner (19; col. 10, lines 28-30); an intermediate structural member (10) interposed between said first and said second polymeric liners, said intermediate structural member being defined by solid segments (17) and openings (15) therebetween such that the first liner is bonded to the second liner (col. 7, lines 56-59) through said openings to form at least one pocket adjacent to said solid segments (33); and a bioactive agent filled within said pocket adjacent to said solid segments of said intermediate structural member (col.9, lines 25-37). The examiner is interpreting this citation to indicate that the bioactive agent or the drug could be located in, and thus filling the pocket (33) located between the solid segment (17) and the polymer liners (14 and/or 19), as it is disclosed in the reference that the drugs may be coated on the polymeric liners (14 and/or 19) and the on the anchoring material (17) used in the stent. This application would place the drugs in the pocket indicated above. (Figures 6, 9)

Regarding claim 2, see the disclosures in claim 1 above, and Figure 6 regarding the cylindrical tubular body with an inner and opposed outer surface.

Regarding claim 3, Sogard et al. discloses the following: said first (14) and said second (19) liners are adheringly joined at a location substantially coextensive with said inner surface of said tubular body (20) (col. 3, lines 28-31; Figure 6).

Regarding claim 4, Sogard et al. discloses the following: the device wherein said solid stent segments include opposed inner and outer segment surfaces defining said inner and outer surfaces of said tubular body and opposed side segment surfaces between said inner and outer segment surfaces (Figure 6).

Regarding claim 5, Sogard et al. discloses the following: the device wherein said second liner (19) is conformed to at least a portion of said side segment surfaces (Figure 6).

Regarding claim 6, Sogard et al. discloses the following: the device wherein said first polymeric liner (14) is positioned about said inner surface of said tubular body (10) (Figure 6).

Regarding claim 7, Sogard et al. discloses the following: the device wherein said second polymeric liner (19) is positioned about said outer surface of said tubular body (10) (Figure 6).

Regarding claim 8, Sogard et al. discloses the following: the device wherein said first liner defines a fluid contacting luminal surface (col. 3, lines 61-64).

Sogard et al. discloses the bioactive agents in claim 9 in col. 9, lines 25-37.

Regarding claim 10, Sogard et al. discloses the following: the device wherein said solid segments of said intermediate structural member are foreign bodies (17), forming said pockets (33) between said first (14) and second (19) liners thereabout (Figure 9).

Regarding claim 11, Sogard et al. discloses the following: the device wherein said bioactive agents filled within said pocket are encapsulated in a polymeric matrix (col. 9, lines 33-37).

Regarding claim 12, Sogard et al. discloses the following: the device wherein said polymeric matrix containing said bioactive agent is a microparticle, microfiber, or microfibril (col. 9, lines 33-37).

Regarding claim 13, Sogard et al. discloses the following: the device wherein said first liner and said second liner are independently selected from the group consisting of synthetic polymer, natural polymer or a combination thereof (col. 5, lines 9-14). It should be noted that this claim describes three possible options for the polymer substances described, and that the examiner only needs to find at least one of synthetic polymer, natural polymer or a combination thereof.

Regarding claim 14, Sogard et al. discloses the following: the device wherein at least one of said first or said second liners is porous (col. 11, lines 24-28).

Sogard et al. discloses the synthetic polymers in claim 15 in col. 5, lines 9-14.

Regarding claim 16, Sogard et al. discloses the following: the device wherein said synthetic polymer is ePTFE (col. 5, lines 9-14).

Regarding claim 17, because the natural polymers were not claimed as a necessity in claim 13, the limitations of claim 17 do not have to be considered.

Regarding claim 18, Sogard et al. discloses the following: the device wherein said natural polymer and said synthetic polymer are biostable or bioabsorbable polymers (col. 5, lines 46-49).

Regarding claim 19, Sogard et al. discloses the following: the device wherein said stent is a biocompatible metal (col. 9, lines 18-20).

Regarding claim 20, Sogard et al. discloses the following: the device wherein said biocompatible metal is selected from the group consisting of stainless steel, platinum, gold, nitinol, tantalum, and alloys thereof (col. 9, lines 18-20).

Regarding claim 21, Sogard et al. discloses the following: the device wherein said first and second liners are of ePTFE (col. 5, lines 9-14).

Regarding claim 22, Sogard et al. discloses the following: the device wherein the porosity of said first liner is different from the porosity of said second liner (col. 11, lines 24-28).

Regarding claim 27, Sogard et al. discloses the following: a composite intraluminal device for delivery of bioactive agents associated therewith to a site of implantation of said device comprising: an elongate stent having generally cylindrical tubular body (10) defined by solid segments (17) and openings (15) between said solid segments, said tubular body defining an inner surface (11) and an opposed outer surface (13); a first polymeric liner (14; col. 9, lines 59-63) positioned about said inner surface of said tubular body; a second polymeric liner (19; col. 10, lines 28-30) positioned about said outer surface of said tubular body; and second polymeric liner being joined to said first liner through said stent openings (col. 7, lines 56-59) to form at least one pocket (33) adjacent to said solid segments (17), said pocket being defined by said first (14) and second (19) liners and said solid segments (17); and a bioactive agent filled within said pocket adjacent to said solid segments of said intermediate structural member (col.9, lines 25-37; Figures 1, 6, 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sogard et al. in view of Lentz et al. (U.S. Patent No. 6,428,571). Sogard et al. discloses the invention substantially as claimed, but it does not specify the internodal distance of the ePTFE covers. Lentz et al. teaches in col. 4, lines 38-48, the methods of manufacturing ePTFE with internodal distances of less than 40 microns for greater radial strength, those with an internodal distance greater than 40 microns for long term patency. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use internodal distances less than 40 microns for radial strength and greater than 40 microns for long term patency.

Response to Arguments

Applicant's arguments filed 12/22/2006 have been fully considered but they are not persuasive. Applicant amended language in claims 1 and 27 to indicate that the bioactive material fills the pocket of the device. As described above, the examiner is interpreting this citation to indicate that the bioactive agent or the drug could be located in, and thus filling the pocket (33) located between the solid segment (17) and the polymer liners (14 and/or 19), as it is disclosed in the reference that the drugs may be coated on the polymeric liners (14 and/or 19) and the on the anchoring material (17) used in the stent. This application would place the drugs

in the pocket indicated above. All other dependent claims are rejected for the reasons cited above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
February 17, 2007

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER